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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,014	02/29/2000	Patrick F. Coleman	09197-008810US	1609

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Brian W Poor
Townsend and Townsend and Crew LLP
Two Embarcadero Center
8th Floor
San Francisco, CA 94111

EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/515,014	COLEMAN ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-28* is/are pending in the application.

4a) Of the above claim(s) *13,14 and 16-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1648, Exr. Mosher.***Election/Restrictions***

The elected species of method using SEQ ID NO:3 is now allowable, because of applicant's amendment. However, the "generic" claims (actually Markush claims) are not allowable, for the reasons given below.

Claims 13-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/4/2002. Applicant argues that claims 26-28 are related to the originally claimed invention as combination/subcombination, and as such do not constitute an undue burden. If the combination relied upon SEQ ID NO:3 for patentability, then examination of the combination would not pose an undue burden. However, the combination could rely for patentability on the combination of pol peptide with HIV1 and HIV2 env polypeptides, or on the patentability of any of the other sequences recited in the claims (see as evidence claims 27 and 28). Since applicant has already received action on the invention of SEQ ID NO:3, and is now receiving an action on another species in the original Markush group, further extension of the search is seen as unduly burdensome.

Claim Rejections - 35 USC § 112

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record. Although a previous Advisory action indicated that this rejection would be withdrawn, the rejection was made again in the subsequent nonfinal office action. The instant examiner is still uncertain regarding the metes and bounds of the claimed invention, after reading the specification and applicant's arguments of record. On the one hand, the general tenor of applicant's arguments have indicated that the intent is to mimic the immunological properties of the SEQ 3 peptide. However, applicant quotes the specification as saying that the polypeptide "need not be identical to any particular HIV-1 of HIV-2 polypeptide sequence, so long as the subject compound is able to immunologically mimic an epitope of the pol region of at least one of the strains of the HIV-2 of HIV-2 virus." Applicant also states that in certain situations where regions of HIV are structurally polymorphic, "it may be desirable to vary one or more particular amino acids to more effectively mimic the differing epitopes of the different retroviral strains." So, do the modifications include or exclude variations that "more effectively mimic the differing epitopes of the different retroviral strains?" In other words, how much immunological distinctiveness is encompassed within "substantially all of the immunological reactivity?" Does the modified peptide have to react with antibodies directed against the same sequence, or is it open to peptides that react only with antibodies directed against the same polymorphic region? Is it open to peptides that have the HIV-2 version of the same region? Since the SEQ ID NO:3 peptide is unexpectedly superior to a similar prior

art peptide, is that unexpected superiority required or not by "substantially all"? Although the term "substantially" is used in the art and in patent claims, claims must set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity so the public is informed of the boundaries of what constitutes infringement of the patent. In this case, the examiner remains confused as to what subject matter is circumscribed by modifications which "retain substantially all of the immunological reactivity" in the context of applicant's specification. In addition, it is noted that claims 6 and 7 are unclear because they are drawn to subject matter that is outside the scope of parent claim 1. If the polypeptide of claim 1 is modified by substitution, or by addition anywhere except the termini, the polypeptide no longer has the sequence recited in claim 1, and is excluded from the scope of claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Cosand et al US 5075211. In the patent, peptide II (123) is less than 60 residues long, and contains applicant's SEQ ID NO: 2. The reference teaches an assay using the peptide to detect HIV-1 antibodies, see Table 1. Therefore the reference renders generic claims 1 and 12 unpatentable. Dependent claims 3, 5, 8, and 9 are also anticipated by the same patent. Also, patent peptides II and IIa (123 and 124) meet the

limitations of claims 6 and 7, since they qualify as substitution modifications of applicant's peptide SEQ ID NO: 5 and peptide II qualifies as an addition modification to applicant's SEQ ID NO:2. Therefore claims 6 and 7 are also anticipated.

Claim Rejections - 35 USC § 103

Claims 2, 4, 10, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosand et al US 5075211. Cosand explicitly suggests an assay with the peptide conjugated to a macromolecule, see column 5, lines 45-54, as required by claim 2. Cosand explicitly suggests radioactive and fluorescent labels as required by claims 10-11, see column 7, lines 12-28. Cosand does not discuss immunoprecipitation, but this is a conventional immunodetection step. Therefore, the invention of these claims is seen as prima facie obvious, absent unexpected results.

Allowable Subject Matter

Claims 1-5, 8-12 would be allowable if limited to SEQ ID NO:3. Claim 26 would be rejoined and allowable if it were limited to SEQ ID NO:3 for the HIV-1 polymerase peptide.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/18/06

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER